

**DETAILED ACTION**

***Response to Amendment***

Receipt is acknowledged of applicant's amendment filed. Claims 1-66 have been canceled without prejudice. Claims 67-74 are pending and an action on the merits is as follows.

Applicant's arguments with respect to claims 67-74 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 67-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuppy (US patent 5755709), herein after referred to as C, in view of Paradis (US PN 5688253), herein after referred to as P.

Regarding **Claim 67**, **C** discloses a catheter (**30**) having a catheter hub (**40**, the rear of the catheter) and an axial through channel with a proximal end portion a needle assembly including a needle (**18**, needle) with a distal sharp point, which extends through said catheter channel, and a safety means (**Fig. 15**, the needle has been withdrawn into the safety cover) having a protector for protecting said needle distal sharp point after introducing said catheter into a blood vessel, wherein said needle assembly is in a protected position when said needle is protected by said protector, wherein in said protected position said needle assembly has a distal end and a proximal end

**C** fails to disclose the cap and the use of a luer lock

However, **P** teaches a luer lock (**38**) catheter cap (**38e**, attachable to the catheter) having a tapered male luer member (**Fig. 1D**) with a tapered end for occluding a proximal opening of said catheter after the transposition of said needle to said protected position, said catheter cap being detachably mounted on said needle assembly; and mounting means for detachable mounting of said catheter cap on said needle assembly, (**Fig. 1C**) wherein said mounting means includes stabilizing means(**Fig. 1C**, once the cap is completely screwed on, it can no longer be moved axially) that prevents rotation of said tapered male luer member with respect to said needle assembly when mounting said catheter cap onto said catheter, and wherein when said needle assembly is in said protected position said catheter cap is positioned at either of said ends of said needle assembly, and said tapered end of said tapered male luer member is directed proximally when said catheter cap is positioned at said

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proximal end of said needle assembly and distally when said catheter cap is positioned at said distal end of said needle assembly.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the construction as taught by **P**, since **P** states at Column 7, lines 60-67 that such modification would reduce exposure to blood. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught in **P**, to improve the device of **C** for the predictable result of making it safer to use.

5. Claims 68-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over **C** and **P**, in view of Cuppy (US pg Pub 2004/0181192), herein after referred to as **D**.

**Regarding Claim 68, C and P** discloses the invention as seen above except for the second mounting element

However, **D** discloses has first and second mounting elements (**90 and 100**) one of which is disposed on said needle assembly and the other on said catheter cap, wherein said stabilizing means is made as at least one slot (**100**, threading) and at least one projection, (**90**) one of which slot and projection is located on said first mounting element and the other of which slot and projection is located on said second mounting element wherein said projection slidably enters said slot

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use multiple mounting elements, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

Regarding **Claim 69**, D discloses catheter cap is detachably retained on said needle assembly by friction between said first and second mounting elements. (**Fig. 2**)

Regarding **Claim 70**, D discloses shielding means (**16**) preventing said tapered luer member from accidental contact with an operator, wherein said shielding means is made as a shielding wall enclosing said tapered male luer member and protruding beyond said tapered end

Regarding **Claim 71**, D discloses catheter cap is disposed on said protector. (**Fig. 2**)

Regarding **Claim 72**, D discloses a hub, (**Fig. 2**) and wherein said catheter cap is disposed on said hub.

Regarding **Claim 73**, D discloses one of said mounting elements is disposed on said needle assembly and forms a receptacle in which said catheter cap is housed and wherein said receptacle acts as said shielding means. (**Fig. 2**)

Regarding **Claim 74**, D discloses a thread for fixing said catheter cap onto said catheter. (**100**, threading)

Applicant's arguments filed have been fully considered but they are not persuasive.

#### *Response to Arguments*

**Applicant states**, the combination fails to teach that the catheter cap is detachable as claimed in applicant's application. However, as seen from the rejection

above the modification of making an element seperable is a well known alteration found in the art. The rejection is maintained on the grounds seen above.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN K. HOLLOWAY whose telephone number is (571)270-3862. The examiner can normally be reached on 8-5, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ian K Holloway/

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Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763